

AUG 14 1996

K962162

510(k) Summary

Proprietary Name: Dall-Miles Trochanter Cable SuperGrip

Common Name: Bone Fixation Cerclage

Classification Name and Reference: Bone Fixation Cerclage  
21 CFR 888.3010

Proposed Regulatory Class: Class II  
Device Product Code: OR(87) JDQ

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The Dall-Miles Trochanter Cable Grip described in this submission is a modification of the original Dall-Miles Cable Grip cleared in (K 872224). The Grip component provides for trochanteric reattachment following osteotomy in Total Hip Arthroplasty. The proximal hooks of the Grip are placed over the top of the trochanter and secured by passing Dall-Miles cables through the holes and crimping them in place.

The modification to the Grip reduces the angle that the cable exits the Grip, thereby relieving potential stress concentrations in the cable.

The substantial equivalence of the Dall-Miles Trochanter Cable Grip is based on the equivalence in intended use, materials, design, operational principles, and indications and contraindications to Howmedica's original Dall-Miles Cable Grip System (K 872224 and K 900926) and Biomet Medical Products' BMP Cable System.